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Minnesota Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Actions

No formal disciplinary actions were concluded by the Minnesota Board of Pharmacy during the three-month period of December 2002 through February 2003.

Renewal Reminder

Board of Pharmacy inspectors continue to report finding pharmacy technicians working without a current technician registration. All technicians are reminded that they are not allowed to work as a pharmacy technician without a valid registration with the Board. Technician registrations were due to be renewed no later than January 1, 2003. For new technicians, original registration must take place before employment as a technician commences.

Minnesota pharmacists are also reminded that March 1, 2003, was the due date for renewal of personal licenses to practice pharmacy. As in the case of pharmacy technicians, it is illegal for a pharmacist to be engaged in the practice of pharmacy without a current license.

Pharmacists-in-charge of pharmacies in Minnesota are responsible for assuring that all pharmacists, pharmacy technicians, and pharmacist interns are properly licensed or registered with the Board at all times.

Drugs from Canada Issue Continues to Grow

The importation of drugs from Canada by individual consumers in the United States is becoming a major issue nationwide and, at the present time, shows no signs of abating.

It is the position of Food and Drug Administration (FDA) that virtually all individual patient prescriptions coming from Canada violate the various provisions of the Food, Drug, and Cosmetic Act. This is true whether the drug was manufactured in Canada and is being imported into the US or whether the drug was manufactured in the US for export to Canada and is being reimported back into the US. Boards of pharmacy, given our limited resources and staffing and our inability to intercept packages coming into the US at the various border-crossing areas, are essentially powerless to deal with the issue. Enforcement of the Food, Drug, and Cosmetic Act in this instance must come from FDA and US Customs.

FDA regularly makes public its position on this issue but, up to now, claims that it, too, has inadequate resources to effectively address the issue. Add to that the political climate in Washington, DC, where Congress has passed legislation that would open up the importation of drugs from Canada if the Secretary of Health and Human Services can certify that the drugs are safe and effective, and you have a situation where FDA lacks any strong support from Congress in its enforcement efforts.

There also seems to be a substantial amount of misinformation published regarding FDA's personal importation policy. FDA's personal importation policies are used to guide the agency's enforcement discretion with respect to imports by individuals of drugs for their personal use. Under certain defined circumstances, as a matter of enforcement discretion, FDA allows consumers to import what would otherwise be illegal drugs. Under this policy, FDA permits individuals and their physicians to bring into the US small quantities of drugs sold abroad for a patient's treatment of a serious condition for which effective treatment may not be available domestically. This approach has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to persons residing in the US. For instance, this policy allows a patient with a rare disease, for which there is no known treatment available in the US, to obtain medication in a foreign country and import it into the United States.

This FDA policy is not intended to allow importation of foreign versions of drugs that are approved in the US, particularly when the foreign versions of such drugs are being commercially advertised to US citizens. Moreover, this policy simply describes FDA's enforcement priorities. It does not change the law and it does not give a license to persons to import or export illegal drugs into the US.

In a recent letter from FDA, it was indicated that there are many potential avenues of civil and criminal liability for parties involved in violations of the act:

> A court can enjoin violations of the act. (21 USC Section 332). A person who violates the act can also be held criminally liable. (21 USC Section 333). A misdemeanor violation of the act is a strict liability offense. (See United States v. Dotterweich, 320 US 277, 284 (1943); 21 USC Section 333(a)(1)). A violation that is committed with intent to defraud or mislead or after a prior conviction for violating the act is a felony. (21 USC Section 333(a)(2)). Separately, it is a felony to knowingly import a drug in violation of the reimport prohibition. (21 USC Section 333(b)(1)(A), 381(d)(1)).
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> Those who can be found civilly and criminally liable include all who cause a prohibited act. (21 USC Section 331). Those who aid and abet a criminal violation of the act, or conspire to violate the act, can also be found criminally liable. (18 USC Section 2 and Section 371).

As can be seen from the above, there are sections of the US Code that address the issue and virtually everyone involved in the importation or reimportation of prescription drugs from Canada including individuals operating the storefront "facilitators," who could be charged with violations if FDA chose to pursue the issue.

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FDA Releases Draft Guidance for Noncontraceptive Estrogen Drug Products

On January 14, 2003, US Food and Drug Administration released a draft labeling guidance for noncontraceptive estrogen drug products that treat moderate to severe vasomotor symptoms and/or moderate to severe symptoms of vulvar vaginal atrophy for new drug applications. The guidance also provides labeling recommendations for the Patient Information leaflet.

A draft of this guidance was first issued in September 1999 (64 FR 52100). However, on September 10, 2002, the Agency withdrew the draft guidance (67 FR 57432) pending consideration of the results from the National Institutes of Health Women's Health Initiative. This second draft is being made available for comment.

Copies of the draft guidance are available from the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Ln, Rockville, MD 20857; phone: 301/827-4573; Internet: www.fda.gov/cder/guidance/index.htm.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication of the *Federal Register* notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Ln, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability published in the *Federal Register*. If you have questions on the content of the draft document, contact Margaret Kober at 301/827-4243.

NABP to Administer FPGEE in June

The National Association of Boards of Pharmacy® (NABP®) is pleased to announce that the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) will be administered as a paper-and-pencil exam on Saturday, June 21, 2003, in four United States locations: Dallas, TX; New York, NY; Northlake (Chicago area), IL; and Oakland, CA. All FPGEE candidates who qualify to sit for the exam have been notified. In November 2002, The FPGEE was halted after NABP detected a security breach of the examination.

Through its investigation proceedings, NABP found a small number of candidates whose scores were invalidated; all other scores were released. NABP member boards were notified of these invalidations.

NABP continues to investigate all matters surrounding the breach of security and reserves the right to deny or revoke Foreign Pharmacy Graduate Examination Committee® certification should the circumstances dictate. These actions are essential to maintain the integrity of the program for all participants.

For more information on the FPGEE administration and answers to frequently asked questions, please visit the Association's Web site at www.nabp.net.

CDER Releases Consumer Brochure Targeting Misuse of Prescription Pain Relievers

The Center for Drug Evaluation and Research (CDER) of the US Food and Drug Administration recently released an informational brochure for consumers targeted at the misuse of prescription pain medication and symptoms of overdose. The brochure explains that prescription pain medication is safe and effective when used correctly and under a doctor's supervision, but, when abused or mixed with alcohol or illegal drugs, one dose can lead to death. According to CDER, combining a prescription pain reliever with other prescription drugs (such as antidepressants) or over-the-counter medications (like cough syrups and antihistamines), can lead to life-threatening respiratory failure.

CDER outlines in *Misuse of Prescription Pain Relievers: The Buzz Takes Your Breath Away. Permanently.* that the most dangerous prescription pain relievers when used incorrectly are those containing drugs known as opioids, such as morphine and codeine. Some common drugs containing these substances include Darvon, Demerol, Dilaudid, OxyContin, Tylenol with Codeine, and Vicodin.

The brochures is available at www.fda.gov/cder/consumerinfo/buzz_brochure.htm.

Final Rules on Security Standards and Modifications to Electronic Data Transactions Standards and Code Sets Published

Two Health Insurance Portability and Accountability Act (HIPAA) final regulations regarding Security Standards and Modifications to Electronic Data Transactions Standards and Code Sets were published in the February 20, 2003 *Federal Register*. The Final Rule adopting HIPAA standards for the security of electronic health information specifies a series of administrative, technical, and physical security procedures for covered entities to use to ensure the confidentiality of electronic protected health information. The standards are delineated into either required or addressable implementation specifications. The Final Rule adopting changes to the HIPAA Electronic Transactions and Code Set Standards modifies a number of the electronic transactions and code sets adopted as national standards under HIPAA, and eliminates the National Drug Code (NDC) code set as the standard for all providers except retail pharmacies. It does not adopt a standard reporting drugs and biologics on non-retail pharmacy transactions.

Under the security standards, health insurers, certain health care providers, and health care clearinghouses must establish procedures and mechanisms to protect the confidentiality, integrity, and availability of electronic protected health information. The rule requires covered entities to implement administrative, physical, and technical safeguards to protect electronic protected health information in their care.

The security standards work in concert with the final privacy standards adopted by the Department of Health and Human Services (HHS) last year and scheduled to take effect for most covered entities on April 14, 2003. The two sets of standards use many of the same terms and definitions in order to make it easier for covered entities to comply.

Covered entities (except small health plans) must comply with the security standards by April 21, 2005. Small health plans have an additional year to comply.

The final transaction modifications rule combines two proposed rules published May 31, 2002. HHS worked extensively with the Designated Standards Maintenance Organizations (DSMOs) to revise the proposed changes to the standards as required by Congress as part of HIPAA.

Major provisions of the Final Rule include:

- Repealing the NDC as the standard medical data code set for reporting drugs and biologics in all non-retail pharmacy transactions.
- Adopting the proposed Addenda to the implementation guides with some technical revisions based upon comments received and consultation with the DSMOs.
- For retail pharmacy transactions:
  - Adopting the National Council for Prescription Drug Programs (NCPDP) Batch Version 1.1 to support the Telecommunications Version 5.1.
  - Adopting the Accredited Standards Committee X12N 835 as the standard for payment and remittance advice and the NCPDP Telecommunications Version 5.1 and NCPDP Batch Version 1.1. Implementation Guides as the standard for the referral certification and authorization transaction.
  - Continuing the use of the NDC code set for the reporting of drugs and biologics.

The rule also adopts modified standards for two transactions that were not included in the proposed rules – premium payments, and coordination of benefits. The modifications were approved by the DMSOs and merely provide explanatory guidance.

Copies of both rules can be viewed at www.cms.hhs.gov/hipaa/hipaa2/default.asp.

Warning! Repackaged Non-drug Substances May Easily be Confused with Medical Products

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with US Pharmacopeia (USP) and Food and Drug Administration (FDA) in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

The Institute for Safe Medication Practices (ISMP) recently received a report where a pharmacist reconstituted AMOXIL (amoxicillin) suspension, 250 mg/5 mL, with an alcohol solution instead of distilled water. At the time of the error, the pharmacy stored plastic bottles containing a 50% alcohol and water solution (used for dermatological preparations) on a counter beside the distilled water bottle used for reconstituting antibiotic suspensions.

Similar errors occurred elsewhere a few years ago in two pharmacies where antibiotic solutions were inadvertently reconstituted with 10% formalin solution (3% formaldehyde and 15% methanol). In both cases, gallon jugs of distilled water were stocked for use in the pharmacy. The empty distilled water jugs were then used as containers for a 10% formalin solution that the pharmacy specially prepared for nearby surgical centers. Empty jugs labeled "distilled water" were accidentally placed with empty jugs labeled "formalin" that were awaiting refill for the surgical centers. After misfilling all the jugs with formalin, employees stored them for transport. When jugs labeled "distilled water" were delivered with the formalin jugs, they were returned to the pharmacy because the surgical center believed distilled water was sent in error. Assuming that the jugs were filled with distilled water, as they were labeled, pharmacy staff then placed them back in stock with other distilled water jugs. Later, each pharmacy accidentally used these mislabeled jugs to refill empty reservoirs intended for distilled water, which were attached to a burette chamber used to measure antibiotic diluent. The burettes emptied at eye level and staff did not smell the formalin as it mixed with the powdered antibiotic suspensions. The errors went undetected until parents called to report the suspensions' strange smell and their children's complaints about the taste. Together, more than 35 children took the tainted antibiotics. Several required hospitalization for vomiting, but none suffered permanent disabilities.

Could something similar happen at your practice site, perhaps with a different non-drug item? During visits to pharmacies and hospitals, we've often noticed soaps, topical substances, tissue fixatives, detergents, and even poisonous substances in bottles that look like drug containers. Who can say for sure that staff would never confuse one of these with an internal or external therapeutic product? Unfortunately, it has happened all too often, in both health care and other settings.

Consider having a policy that forbids the practice of repackaging products in empty drug or solution containers. Even go so far as to poke a hole in empty plastic containers to prevent reuse with another fluid. Perform a risk assessment at your pharmacy to determine if any chemicals could be confused with something else due to the container's color, size, shape, the product's name or packaging, or the solution's color/clarity, and take the necessary steps to reduce the risk of an error. Examine your current supply of chemicals and discard any that haven't been used in years. For those that must remain, do not store them near other drugs or diluents. Make sure that labels clearly indicate the contents. Place bold warning labels on any non-drug products. Do not supply surgical centers with chemicals, which can be obtained more safely through health-related laboratory supply houses. Because non-clinicians (technicians, support staff, etc) also may occasionally be involved in practices that lead to medication errors, allot time during staff meetings to review appropriate patient safety issues discovered within the facility or through information that you learn through our ISMP newsletters. For example, at an upcoming meeting, present the antibiotic suspension case described above. Be sure to include all personnel (clinical and non-clinical, pharmacy and non-pharmacy). Explain why it is dangerous to repackage non-drug substances into empty drug, solution, or irrigation solution containers or to add non-drug substances to these containers. And don't give out any pharmacy bottles or labels to your patients because you do not know how they will be used.

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Until the US Congress takes action to support FDA's enforcement of the Food, Drug, and Cosmetic Act, or until the pricing policies of the major drug companies change, it appears that the issue of drugs from Canada will continue to grow and negatively impact pharmacy practice in the US.

Electronically Transmitted Prescription Orders Becoming More Common

In recent weeks, the Board of Pharmacy office has received several calls from pharmacists seeking clarification of the legality of computer-generated prescriptions, which have been signed electronically by the prescriber. Pharmacists have been seeking input from the Board regarding the legality of these orders.

The Board currently does not have any specific rules relating to computerized physician order entry or electronic prescribing. Thus, the computer-generated prescriptions that are electronically signed by the prescriber and which are generally faxed to a pharmacy directly from a computer in the physician's office are technically legal as long as the drug is not a controlled substance. At the present time, Drug Enforcement Administration (DEA) does not recognize the validity of electronic signatures.

Of concern to pharmacists is the fact that it is extremely difficult to determine the legitimacy of the electronically produced prescription document that appears on the pharmacy's fax machine. Until the issues surrounding electronic signatures and electronically transmitted prescriptions mature and are addressed by DEA's rules and perhaps by rules of the Board of Pharmacy, pharmacists are encouraged to exercise their professional judgment in determining whether or not a call back to a physician's office to verify the authenticity of the prescription is warranted.

HIPAA Privacy Rules Take Effect April 14

HIPAA, the Health Insurance Portability and Accountability Act of 1996, addresses, among other things, the care that health care providers must take in assuring the confidentiality of protected health information.

The application of the HIPAA requirements has been divided into three major areas: privacy rules, transaction rules, and security rules. The effective date for the privacy rules is April 14, 2003.

Every pharmacy in Minnesota must identify a privacy officer who will be responsible for implementation of the HIPAA requirements. The pharmacy's privacy officer is responsible for making sure the pharmacy has a notice of privacy practices that will be followed in that pharmacy and that patients of the pharmacy receive a copy of the policy. The privacy officer must also oversee employee training on the privacy policies, and must make sure that protected health information is not released without the patient's permission.

For instance, each pharmacy must take a look at the manner in which it discards various documents generated by the computer software system that might have patient identities and protected health information on them (ie, are all the various pieces of paper generated during the prescription-filling process shredded?) Pharmacies must also address other privacy-related issues such as: Is your patient-counseling area adequate to prevent eavesdropping by other members of the public while you are counseling your patients? Is the insurance log that you have patients sign designed in such a way that the patient signing the log cannot determine which other patients picked up prescriptions earlier?)

If you have not already done so, you are encouraged to take the steps necessary to implement the HIPAA requirements as soon as possible. Additional information regarding the HIPAA requirements can be obtained through the Minnesota Pharmacists Association, Minnesota Society of Health-System Pharmacists, and from the Board of Pharmacy inspectors.

Boards Elects New Officers for 2003

At its January meeting, the Board of Pharmacy elected a new president and vice president for the 2003 calendar year. Assuming the presidency is Ms Betty Johnson, a community pharmacist from Elbow Lake. Assuming the office of the vice president is Mr Chuck Cooper, director of pharmacy at Hennepin County Medical Center in Minneapolis. Betty and Chuck will serve in their new positions until the January 2004 Board meeting.

The *Minnesota Board of Pharmacy News* is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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